S 1301

Better Medicine for Children Act

Congress: 107 (2001–2003, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Aug 1, 2001
Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Aug 1, 2001)
Official Text: https://www.congress.gov/bill/107th-congress/senate-bill/1301

Sponsor

Name: Sen. Bond, Christopher S. [R-MO]
Party: Republican • **State:** MO • **Chamber:** Senate

Cosponsors

No cosponsors are listed for this bill.

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Aug 2, 2001

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Aug 1, 2001)

Better Medicine for Children Act - Amends the Federal Food, Drug, and Cosmetic Act to establish a second period of market exclusivity for already-marketed drugs.

Amends the Public Health Service Act to require the Secretary of Health and Human Services, in awarding institutional training grants to institutions supporting pediatric training, and in entering into pediatric research loan repayment contracts, to give priority to pediatric speciality areas in which there is significant need.

Expresses the sense of the Senate that the National Institutes of Health should consider the formation of a Pediatric/Developmental Pharmacology Scientific Review Group or Special Emphasis Panel to evaluate Federal grants programs relating to pediatric pharmacology.

Directs the Secretary to develop a list of approved drugs for which: (1) there is no patient or market exclusivity protection; and (2) additional pediatric safety and effectiveness studies are needed. Directs the Secretary to award contracts to entities with appropriate experience for pediatric clinical trials of such drugs.

Establishes a Food and Drug Administration (FDA) contract process for related labeling changes.

Amends the Federal Food, Drug, and Cosmetic Act to: (1) eliminate the user fee waiver for pediatric supplements to a human drug application; (2) provide priority status for pediatric supplements; (3) include neonates within the definition of pediatric studies; (4) provide for dissemination of pediatric supplemental information; and (5) set forth requirements for the additional six-month exclusivity period for new or already-marketed pediatric drugs.

Directs the Secretary to establish an Office of Pediatric Therapeutics within the Office of the Commissioner of Food and Drugs, which shall coordinate all FDA pediatric activities.

Actions Timeline

- **Aug 1, 2001:** Introduced in Senate
- **Aug 1, 2001:** Sponsor introductory remarks on measure. (CR S8597-8599)
- **Aug 1, 2001:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.